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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,476	09/27/2001	Michael Mendez	40977	5080

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EXAMINER	
AKHAVAN, RAMIN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,476	MENDEZ ET AL.	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5-8-2

DETAILED ACTION

Receipt is acknowledged of a response, filed 06/15/2005, amending claim 7. Claims 7 and 32 are currently pending and under consideration in this action. All objections/rejections not repeated herein are hereby withdrawn. Where applicable, a response to Applicant's arguments will be set forth immediately following the body of any objections/rejections repeated herein.

A new ground of rejection is set forth herein below, that is necessitated by material changes to the claims. Since no new grounds of rejection are set forth that were not necessitated by amendment to the claims, **this action is made FINAL**.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. **Claims 7 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

This is a new ground of rejection necessitated by amendment to the claims. Claim 7 recites the limitation "the target polynucleotide in yeast" which lacks sufficient antecedent support in the preceding body or preamble of the claim. The only support present is for *a target polynucleotide*. Therefore, as written, the claim is vague and indefinite as to whether the vector further comprises "*a sequence* for homologous recombination with the target polynucleotide in yeast. ". (emphasis added).

It would be remedial to replace the term "a sequence" with terms that find support in the claim (e.g., "the segments" which would be directed to the first and second segments).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the new rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. **Claims 7 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Elledge et al. (US 6,828,093; see whole document; hereinafter the '093 patent).**

This is rejection is of record and repeated herein. A response to Applicant's arguments is set forth immediately following the body of this rejection.

The claims are drawn to a vector system for cloning large nucleic acids and delivery of the cloned nucleic acid to a target cell, where the composition comprises a first arm with a first selectable marker, a first cyclization element and a first segment homologous to the 5' terminus of a target polynucleotide and a second arm with a second selectable marker, second cyclization element and second segment homologous to the 3' terminus of the target polynucleotide, wherein the target nucleic acid is a virus, particularly DNA virus, more particularly a DNA virus such as adenovirus. The limitation of "first" and "second arm" is interpreted as broadly as reasonable, as such the arms can be contained on different regions of a circular or linear construct.

Furthermore, the limitation "large nucleic acids" is interpreted as broadly as reasonable to mean any sized nucleic acid predicated on the fact that the term is not delimited to any particular fragment size. In addition, the limitation "cyclization" is interpreted as broadly as reasonable in light of the definition provided in the specification (p. 18, last ¶), as any sequence capable of promoting circularization of the vector arms.

The '093 patent teaches recombinant vectors that contain two cyclization elements (i.e., lox sites), two selection markers (e.g., Ampicillin and Kanamycin resistance and a gene of interest that would necessarily contain some portions that are homologous to 5' and 3' regions of said gene. (e.g., Figures, 1, 12, 14, 20 and 24; col. 14, ll. 7-27, 45-65; col. 15, ll. 7-20; col. 15, last ¶ bridging to col. 16; col. 17, ll. 20-65, bridging to col. 18; col. 20, ll. 25-45). In addition, the gene of interest can be DNA from an adeno-associated virus. (col. 21, l. 27). Furthermore, a suitable host for the vector is *E. coli.* (col. 15, l. 66). In sum, the '093 patent anticipates the rejected claims.

Response to Arguments

Applicant's arguments filed 06/15/2005 have been fully considered but they are not persuasive. Applicant's arguments in essence can be summarized into the single assertion that Elledge does not describe a combined expression construct that comprises a sequence for homologous recombination with a target polynucleotide in yeast. (e.g. Remarks, p. 4, full paragraphs 2-3, bridging to p. 5).

As stated above, there is some ambiguity as to how claim 7, as written, is to be interpreted. Notwithstanding the fact that the claims are vague and indefinite, and in the interest of advancing prosecution, the claims are interpreted to mean that the first and second segments

comprise homologous regions to a target polynucleotide. Therefore, the claims are directed to any vector comprising a first and second selectable marker, a first and second cyclization element, a first and second segment homologous to the 5' and 3' of a target polynucleotide and where the target polynucleotide is of a selected group of viruses, including adeno-associated virus.

With respect to the limitation "in yeast", it is respectfully pointed out that whether the target polynucleotide is in yeast, is *in vitro*, or is in some other cell does not change the structural characteristics of the vector compositions. In other words, the limitation "in yeast" is of little moment in determining whether a prior art composition comprises the claimed structural limitations.

As stated in the body of the rejection, the '093 patent (Elledge) teaches a composition that meets the claimed structural limitations of the instant claims. However, Applicant asserts that merely because the prior art composition teaches the existence of an AAV gene in the disclosed vector, this does not equate to anticipation of a first and second segment, each respectively homologous to the 3' and 5' terminus of target polynucleotide, wherein the target polynucleotide is from AAV. (Remarks, p. 4, last ¶ bridging to p. 5). The fact of the matter is that a sequence comprising an AAV gene would undeniably comprise at least a first and second region that would be homologous to a target AAV sequence comprising at least similar nucleic acid regions. Therefore, if a vector comprises the necessary AAV gene, it is of little consequence that the target sequence is present in a yeast cell or for example bound to a membrane. The salient point is that the prior art composition comprises the same structural limitations as recited in the instant claims.

It appears that Applicant is at least implying in part that the prior art composition is not intended for the same use, as that which is contemplated in the instant disclosure. However, as the MPEP 2122 states: "In order to constitute anticipatory prior art, a reference must identically disclose the claimed compound, but *no utility need be disclosed by the reference. In re Schoenwald*, 964 F.2d 1122, 22 USPQ2d 1671 (Fed. Cir. 1992)" (emphasis added). Therefore, that the '093 patent discloses an identical composition comprising all the required structural elements supports the assertion that the '093 patent anticipates the rejected claims. Thus, the rejection is maintained.

Conclusion

No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached between 8:30-5:00, Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD, can be reached on 571-272-0781. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300 for regular communications and 703-872-9307 for After Final communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully submitted,

Ray Akhavan/AU 1636

DAVID GUZO
PRIMARY EXAMINER